## UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF INDIANA

SERGIO GROBLER, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

INOTIV, INC., ROBERT W. LEASURE, and BETH A. TAYLOR,

Defendants.

Case No: 4:22-cv-00045

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Sergio Grobler ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, and announcements made by Defendants, public filings, wire and press releases published by and regarding Inotiv, Inc. ("Inotiv" or the "Company"), the proceeding styled *United States of America v. Envigo RMS, LLC*, case no. 6:22-cv-00028-NKM (W.D. Va.), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### **NATURE OF THE ACTION**

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Inotiv securities between September 21, 2021 and June 13, 2022, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by

Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

#### **JURISDICTION AND VENUE**

- 2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).
- 3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).
- 4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.
- 5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

#### **PARTIES**

- 6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Inotiv securities during the Class Period and was economically damaged thereby.
- 7. Inotiv purports to be a contract research organization which provides nonclinical and analytical drug discovery and development services and research models and related products and services. On September 21, 2021, Inotiv announced the acquisition of Envigo RMS, LLC

("Envigo"). On November 5, 2021, Inotiv completed the acquisition of Envigo which is now a direct, wholly owned subsidiary of Inotiv.

- 8. The Company is incorporated in Indiana and its head office is located at 2701 Kent Avenue, West Lafayette, Indiana 47906. Inotiv's common stock trades on the NASDAQ Exchange ("NASDAQ") under the ticker symbol "NOTV".
- 9. Defendant Robert W. Leasure ("Leasure") has served as the Company's Chief Executive Officer, President, and a Director since January 2019.
- 10. Defendant Beth A. Taylor ("Taylor") has served as the Company's Chief Financial Officer and Vice President of Finance since March 2020.
- 11. Defendants Leasure and Taylor are collectively referred to herein as the "Individual Defendants."
  - 12. Each of the Individual Defendants:
    - (a) directly participated in the management of the Company;
    - (b) was directly involved in the day-to-day operations of the Company at the highest levels;
    - (c) was privy to confidential proprietary information concerning the Company and its business and operations;
    - (d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
    - (e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

- (f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (g) approved or ratified these statements in violation of the federal securities laws.
- 13. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.
- 14. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondent superior* and agency principles.
- 15. The Company and the Individual Defendants are collectively referred to herein as "Defendants."

#### **SUBSTANTIVE ALLEGATIONS**

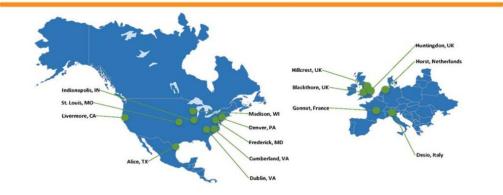
#### Materially False and Misleading Statements Issued During the Class Period

16. On September 21, 2021, during market hours, Inotiv filed with the SEC a current report on Form 8-K which was signed by Defendant Taylor. The Form 8-K included an investor presentation which touted Envigo and its animal services and abilities, including in the following slides:

### Envigo at a Glance



### Strong RMS Footprint Operating Globally



Envigo has Strategically Positioned Itself as a Leader in Research Models Services in Key Research Locations

- Domestic and international presence extends to 8 U.S. states, the United Kingdom, the Netherlands, Italy, France and Israel
- Corporate headquarters located in Indianapolis, Indiana, supported by surrounding small-scale operating facilities





17. On September 21, 2021, Inotiv issued a press release entitled "Inotiv, Inc. and Envigo Propose to Join Forces to Enhance Research and Drug Discovery Solutions", that was also attached to the above-mentioned Form 8-K, which stated the following, in pertinent part, regarding Envigo and touting its animal services and abilities:

Inotiv, Inc. (NASDAQ:NOTV) (or "Inotiv"), a leading contract research organization (CRO) specializing in nonclinical and analytical drug discovery and development services, and Envigo RMS Holding Corp. (or "Envigo"), a leading global provider of research models and services, today jointly announced that they have entered into an agreement for Inotiv to purchase Envigo.

\* \* \*

"Envigo has a long history and broad expertise supplying critical research models and services to the scientific community," said Envigo CEO, Adrian Hardy. "Our diverse client base of CROs, pharmaceutical, government and academic institutions and Inotiv's biopharma clients will be able to utilize leading research models and services from Envigo, including genetically engineered models and services (GEMS), contract breeding services, Teklad laboratory animal diets, surgical services, custom antibody services, and large and small research models."

(Emphasis added.)

18. On November 5, 2021, Inotiv issued a press release entitled "Inotiv, Inc. Completes Purchase of Envigo" which stated the following, in pertinent part, regarding Envigo and touting its growth opportunities, and its animal services and abilities:

Inotiv, Inc. (NASDAQ:NOTV) (or "Inotiv"), a leading contract research organization (CRO) specializing in nonclinical and analytical drug discovery and development services and products, today announced it has completed the acquisition of Envigo RMS Holding Corp. (or "Envigo"), a leading global provider of research models and services.

\* \* \*

"The combination of Inotiv and Envigo allows drug developers to work with one organization for the entirety of discovery and nonclinical development, while getting the same highly personalized service that characterizes both companies. The combined company has excellent growth opportunities, and we plan to continue to make investments for organic growth while selectively pursuing strategic acquisitions," said Inotiv President and CEO Robert Leasure, Jr. "Envigo has a long history and deep experience with supply of critical research models, which will be integrated with Inotiv's range of nonclinical and analytical services. This provides clients with a unique, full-spectrum discovery-to-approval solution to meet the increasing growth and innovation in biopharma and demand for specialty and disease-specific models."

With Inotiv and Envigo combined, drug developers and researchers will receive:

- Deep expertise and expanded access to scientists across the discovery and preclinical continuum, reducing nonclinical lead times and providing enhanced project delivery
- Access to a wide range of high-quality small and large research models for basic research and drug discovery and development, as well as models for specialized disease and therapeutic areas
- The ability to run selected nonclinical studies directly on-site at closely located research model facilities and access to innovative genetically engineered models and services (GEMS) solutions

"The transaction establishes a discovery and preclinical leader with the unique ability to leverage an expansive research model portfolio," said, Adrian Hardy, Ph.D. who served as Envigo's CEO. "The combined companies will create value for both our client bases with a uniquely differentiated, scaled, and broad service offering. We're thrilled to be able to continue to meet expanding client needs required to bring new molecules to market."

(Emphasis added.)

19. On October 5, 2021, Inotiv filed with the SEC a proxy statement on Schedule 14A which stated the following, in pertinent part, regarding Inotiv's due diligence, and also Envigo while touting its animal services and abilities:

Envigo is primarily a products business that provides research-quality animals for use in laboratory tests, as well as standard and custom laboratory animal diets and bedding and other associated services for contract research organizations, biopharmaceutical companies, universities, governments and other research organizations. It provides customers with laboratory animals used in basic research and product development and non-clinical testing of compounds to support the development and approval of new medicines. Utilizing its portfolio of products, Envigo enables its customers to create a more flexible product development model and reduce their costs, enhance their productivity, and increase speed to market. Envigo's vision, working together to build a healthier and safer world, includes helping its customers meet certain regulatory requirements in order to bring lifesaving and life-enhancing new medicines to patients. For more information about Envigo, please see the sections entitled "Proposal 2 — Approval of the Merger Share Issuance Proposal — Envigo Overview" and "— Envigo's Management's Discussion and Analysis of Financial Condition and Results of Operations."

\* \* \*

#### **Envigo Overview**

Envigo is primarily a products business that provides research-quality animals for use in laboratory tests, as well as standard and custom laboratory animal diets and bedding and other associated services for contract research organizations, biopharmaceutical companies, universities, governments and other research organizations. It provides customers with laboratory animals used in basic research and product development and non-clinical testing of compounds to support the development and approval of new medicines. Utilizing its portfolio of products, Envigo enables its customers to create a more flexible product development model and reduce their costs, enhance their productivity, and increase speed to market. Envigo's vision, working together to build a healthier and safer world, includes helping its customers meet certain regulatory requirements in order to bring life-saving and life-enhancing new medicines to patients.

Envigo is a leading commercial provider of RMS [Research Models and Services] products and services globally and has been supplying research models since 1931. With over 130 different strains, Envigo is a global leader in the production and sale of the most widely used rodent research model strains, and is able to offer a broad

range of species in its sector. Envigo also manufactures and sells premium Teklad brand diets for laboratory animals and provides a variety of related services that are designed to assist clients in the use of animal models in research and development. Envigo maintains production centers, including barrier and isolator facilities, in the U.S., U.K., mainland Europe, and Israel.

Envigo's RMS business is comprised of (1) Research Models, (2) Diets and Bedding, and (3) Research Model Services.

Research Models. The research models business is comprised of the commercial production and sale of laboratory animals and research models, principally purpose-bred rats and mice and large animal models (NHPs, canines and rabbits) for use by researchers. Envigo provides models to numerous customers around the world, including many academic institutions, government agencies, biopharmaceutical companies, and contract research organizations. Envigo has a global footprint with production facilities strategically located in six countries. Its operations are located in close proximity to its customers, enabling Envigo to provide consistent customer service with a high degree of focus on animal welfare.

Envigo's research models include standard stocks and strains, immunocompromised models (which are useful for oncology research), disease models (which are in demand as early-stage research tools) and genetically-engineered models ("GEMs", which are often created for specific research projects). The FDA and other regulatory agencies require that the safety and efficacy of new drug candidates be tested on research models like ours prior to product registration. As a result, Envigo's research models are an essential part of the drug research and development process.

\* \* \*

Certain of Envigo's models are proprietary, disease-specific rodent models used to research treatments for diseases such as diabetes, obesity, cardiovascular and kidney disease.

Large Research Models. Envigo's large animal portfolio includes non-human primates, which we call "NHPs", canines and rabbits. NHPs are generally imported into the U.S. from Asia and Africa, with very limited breeding in the U.S. Envigo operates a large quarantine facility in the U.S. to house and clear these imported animals, ensuring they have high health status before onward shipment to customers. NHPs are used by Envigo's customers primarily for the safety testing of new biological therapies. Canines are purpose-bred in the U.S. and used primarily for the safety testing of new chemical therapies. Rabbits are bred in both the U.K. and U.S. and utilized primarily for the reproductive safety testing of potential new therapies.

\* \* \*

Between July 20, 2021 and August 20, 2021, Mr. Leasure and Dr. Sagartz visited Envigo locations in Missouri, Virginia, Maryland, Pennsylvania, Texas, San Francisco, Indiana, Wisconsin, The Netherlands and England.

(Emphasis added.)

20. The October 5, 2021, proxy statement merely listed failure to comply with governmental regulations as a risk, without discussing the ongoing violations, stating the following, in pertinent part:

#### **Legal and Regulatory Risk Factors**

Failure to comply with applicable governmental regulations could harm our business.

Envigo is subject to a variety of governmental regulations, particularly in the United States, Europe, and the United Kingdom, relating to animal welfare and the conduct of our business, including the U.K. Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 and U.S. USDA Animal Welfare Regulations. Our facilities are therefore subject to routine formal inspections by regulatory and supervisory authorities, including the U.S. FDA, the U.S. USDA and the U.K. Home Office, as well as by representatives from customer companies.

Envigo expends significant resources on compliance efforts. Regulations and guidance worldwide concerning the production and use of laboratory animals for research purposes continue to be updated. ... Similarly, guidance has been and continues to be developed for other areas that impact the biomedical research community on both a national and international basis, including transportation, import and export requirements of biological materials, and animal housing and welfare. Certain of our customers may require us to comply with any new guidance in advance of our implementation as a condition to being awarded contracts. Conforming to new guidelines may result in increased costs attributable to adding or upgrading facilities, the addition of personnel to address new processes and increased administrative burden.

(Emphasis added.)

21. On December 21, 2021 the Company filed with the SEC its annual report for the year ended September 30, 2021 (the "2021 Annual Report") signed by Defendants Leasure and

Taylor. Attached to the 2021 Annual Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Leasure and Taylor attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.

22. The 2021 Annual Report stated the following, in pertinent part, stated the following, in pertinent part, regarding Envigo and touting its animal services and abilities:

On September 21, 2021, we entered into a definitive agreement and plan of merger (the "Merger Agreement") pursuant to which we agreed, subject to certain closing conditions, to acquire Envigo RMS Holding Corp. ("Envigo"), a provider of research-quality animals for use in laboratory tests, as well as standard and custom laboratory animal diets and bedding and other associated services for contract research organizations, biopharmaceutical companies, universities, governments and other research organizations, by merger of Envigo with a newly formed, wholly owned subsidiary of ours (the "Envigo Acquisition").

\* \* \*

#### **Nonclinical Services**

Our animal research facilities are subject to a variety of federal and state laws and regulations, including The Animal Welfare Act and the rules and regulations enforced by the United States Department of Agriculture ("USDA") and the National Institutes of Health ("NIH"). These regulations establish the standards for the humane treatment, care and handling of animals by dealers and research facilities. Our animal research facilities maintain detailed standard operating procedures and other documentation necessary to comply with applicable regulations for the humane treatment of the animals in our custody. If the USDA determines that our equipment, facilities, laboratories or processes do not comply with applicable Animal Welfare Act standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For continued noncompliance, the USDA may impose fines, suspend and/or revoke animal research licenses or confiscate research animals. In addition to being licensed by the USDA as a research facility, we are also accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International and have registered assurance with the NIH.

\* \* \*

#### Overview

Envigo is primarily a products business that provides research-quality animals for use in laboratory tests, as well as standard and custom laboratory animal diets and bedding and other associated services for contract research organizations, biopharmaceutical companies, universities, governments and other research organizations. Envigo provides our customers with laboratory animals used in basic research and product development and non-clinical testing of compounds to support the development and approval of new medicines. Utilizing its portfolio of products, Envigo enables our customers to create a more flexible product development model and reduce their costs, enhance their productivity, and increase speed to market. *Envigo's vision, working together to build a healthier and safer world, includes helping our customers meet certain regulatory requirements* in order to bring lifesaving and life-enhancing new medicines to patients.

Envigo is the second largest commercial provider of research model products and services globally and has been supplying research models since 1931. With over 130 different strains, Envigo is a global leader in the production and sale of the most widely used rodent research model strains, and is able to offer the broadest range of species in our sector. Envigo also manufactures and sells premium Teklad brand diets for laboratory animals and provides a variety of related services that are designed to assist our clients in the use of animal models in research and development. Envigo maintains production centers, including barrier and isolator facilities, in the U.S., U.K., mainland Europe, and Israel.

#### Envigo's Market

The market for Envigo's services includes contract research organizations, biopharmaceutical companies, universities, governments and other research organizations.

Envigo offers a broad range of research-quality small and large animal models, research-quality standard and custom diets, as well as an associated suite of services to support the research community. Envigo's portfolio of products and services provides our customers vital support in their efforts to perform fundamental life sciences research, as well as developing life-saving and life-enhancing new medicines.

\* \* \*

#### Research Models and Services ("RMS")

Envigo's RMS business is comprised of (1) Research Models, (2) Diets and Bedding, and (3) Research Model Services.

Research Models. Envigo's research models business is comprised of the commercial production and sale of laboratory animals and research models, principally purpose-bred rats and mice and large animal models (NHPs, canines

and rabbits) for use by researchers. Envigo provides these models to numerous customers around the world, including many academic institutions, government agencies, biopharmaceutical companies, and contract research organizations. Envigo has a global footprint with production facilities strategically located in six countries. Envigo's operations are located in close proximity to our customers, enabling it to provide top-tier customer service with a high degree of animal welfare.

Envigo's research models include standard stocks and strains, immunocompromised models (which are useful for oncology research), disease models (which are in demand as early-stage research tools) and genetically-engineered models ("GEMs", which are often created for specific research projects).

\* \* \*

Large Research Models. Envigo's large animal portfolio includes NHPs, canines and rabbits. NHPs are generally imported into the U.S. from Asia and Africa, with very limited breeding in the U.S. Envigo operates a large quarantine facility in the U.S. to house and clear these imported animals, ensuring they have high health status before onward shipment to customers. NHPs are used by our customers primarily for the safety testing of new biological therapies. Canines are purposebred in the U.S. and used primarily for the safety testing of new chemical therapies. Rabbits are bred in both the U.K. and U.S. and utilized primarily for the reproductive safety testing of potential new therapies.

\* \* \*

#### Envigo's Competitive Strengths

We believe that Envigo is well positioned to capitalize on favorable trends in the research industry and provide differentiated solutions to our customers based on the key competitive strengths set forth below:

. .

• Commitment to animal welfare. Envigo is on the forefront of humane care of laboratory animals and implementation of the "3Rs" (Replacement, Reduction and Refinement). Envigo maintains high standards of animal welfare as evidenced by its strong compliance record with regulators across the globe. Envigo frequently advises our customers in matters relating to animal welfare, including enrichment, housing and animal husbandry.

\* \* \*

#### *Industry Support and Animal Welfare*

Envigo is committed to delivering first-class health and genetic quality, operational performance and customer service. High standards of animal welfare are vital to each of these, and so are integral to Envigo's business success.

Envigo has been at the forefront of animal welfare improvements and the humane care of laboratory animals. Envigo is a leading advocate for implementation of the 3Rs (Replacement, Reduction and Refinement). *Members of Envigo's scientific and technical care staff undertake continuing professional development in the field of laboratory animal science, with special focus to animal welfare and the 3Rs, and they are encouraged to publish and present within the scientific community.* 

Envigo has formed an internal Institutional Animal Care and Use Committee, comprising staff from many disciplines within Envigo, in addition to external representation, to comply with applicable regulations and provide strict oversight of animal welfare matters. Envigo's animal production facilities in the U.S. and the Netherlands, are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International ("AAALAC"), a private, non-profit, international accrediting organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. Envigo's facilities are routinely inspected by government agencies tasked with enforcing animal welfare regulations. ...

Laboratory animals remain an essential component in the research and development that our customers conduct. They further our knowledge of living systems and help in the discovery and development of products that can save or enhance people's lives. Envigo works with the scientific community to improve our understanding and promote best practice in the care and welfare of research animals. As providers of research models to the research community, Envigo is responsible to our customers and the public for the health and well-being of the animals in our care.

#### Environmental, Social and Governance Principles

Envigo endeavors to fully comply with all applicable environmental, social and governance criteria. *Envigo's strengths include, among other areas*, its dedicated responsibility for environmental issues; *its waste management and hazardous substances handling procedures*; labor and human rights policies (including employee health and safety); customer protection policies and efforts; and policies on anticorruption and bribery.

Animal Welfare. Envigo maintain policies regarding animal welfare. Given Envigo's line of business, animal welfare is one of its highest priorities, as it is crucially important from both an ethical and a good business practices perspective.

\* \* \*

#### Regulatory Matters

As Envigo's business operates in a number of distinct operating environments and in a variety of locations worldwide, Envigo is subject to numerous, and sometimes overlapping, regulatory environments.

The Animal Welfare Act ("AWA") governs the care and use of certain species of animals used for research in the U.S. other than laboratory rats, mice and birds. For regulated species, the AWA and the associated animal care regulations require producers and users of regulated species to provide veterinary care and to utilize specific husbandry practices such as cage size, shipping conditions, sanitation and environmental enrichment to assure the welfare of these animals. Separately, facilities using live vertebrate animals in research funded by the U.S. Public Health Service ("PHS") must also adhere to the PHS Policy on Humane Care and Use of Laboratory Animals and follow the Guide for the Care and Use of Laboratory Animals produced by the Institute for Laboratory Animal Research.

Envigo is subject to licensing and registration requirement standards set by the United States Department of Agriculture ("USDA") and similar agencies in other countries for the care and use of regulated species. ... Envigo is regularly consulted and inspected by the relevant national authorities in order to ensure continued compliance with the legal requirements in each nation in which it operates.

Envigos import and export of animals and its operations in foreign countries are subject to international agreements and conventions, as well as a variety of national, regional, and local laws and regulations, which establish the standards for the humane treatment, care, handling and transport of animals by dealers and research facilities.

(Emphasis added.)

23. The 2021 Annual Report merely noted that an Envigo facility was appealing certain non-compliance findings, without discussing the ongoing violations, stating the following, in pertinent part:

We are subject to periodic inspections by regulatory authorities which could lead to enforcement actions if those authorities determine that our facilities or procedures do not meet applicable requirements.

We are subject to periodic inspections by regulatory authorities, including the FDA and the USDA. As part of these inspections, the regulatory authorities seek to determine whether our facilities and operations comply with applicable laws and

regulations. Adverse findings as a result of these inspections could lead to enforcement actions, including substantial fines, warning letters that require corrective action (including potential facilities improvement requirements), revocation of approvals, exclusion from future participation in government healthcare programs, criminal prosecution and even the denial of the right to conduct business. During the period from July through December 2021, one of the Envigo's U.S. facilities was inspected on several occasions by the USDA. Following the inspection, USDA issued inspection reports with findings of noncompliance with certain USDA laws and regulations. Envigo formally appealed certain of the findings and the USDA has indicated it intends to conduct a formal investigation. The inspections and/or the investigation could lead to enforcement action resulting in penalties that could include a temporary restraining order or injunction, civil and/or criminal penalties, and/or license suspension or revocation. The imposition of any of these penalties or other restrictions on our business as a result of the inspections could adversely affect our business reputation and could have a material adverse impact on our financial condition, results of operations and stock price.

#### (Emphasis added.)

- 24. On May 16, 2022, the Company filed with the SEC its periodic report for the quarter ended March 31, 2022 (the "1Q22 Report") signed by Defendants Leasure and Taylor. Attached to the 1Q22 Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Leasure and Taylor attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.
- 25. The 1Q22 Report stated the following, in pertinent part, merely stated the following, in pertinent part, regarding the investigation into an Envigo facility without noting that the facility would be shut down within a month nor the ongoing issues:

#### Government Investigations

During the period from July 2021 through March 2022, one of Envigo's U.S. facilities was inspected on several occasions by the U.S. Department of Agriculture ("USDA"). USDA issued inspection reports with findings of non-compliance with certain USDA laws and regulations. *Envigo formally appealed certain of the findings, and has made multiple remediations and improvements at the facility, of which it has kept USDA apprised.* USDA has indicated it intends to conduct a

formal investigation. The inspections and/or the investigation could lead to enforcement action resulting in penalties that could include a temporary restraining order or injunction, civil and/or criminal penalties, and/or license suspension or revocation. As of the 10-Q filing date, no investigation had been initiated.

(Emphasis added.)

26. The statements contained in ¶¶ 16-25 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Envigo and Inotiv's Cumberland, Virginia facility (the "Cumberland Facility") engaged in widespread and flagrant violations of the AWA; (2) Envigo and Inotiv's Cumberland Facility continuously violated the AWA; (3) Envigo and Inotiv did not properly remedy issues with regards to animal welfare at the Cumberland Facility; (4) as a result, Inotiv was likely to face increased scrutiny and governmental action; (5) Inotiv would imminently shut down two facilities, including the Cumberland Facility; (6) Inotiv did not engage in proper due diligence; and (7) as a result, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

#### THE TRUTH EMERGES

27. On May 20, 2022, after market hours, filed with the SEC a current report on Form 8-K which announced the search and seizure at the Cumberland Facility and the subsequent DOJ Complaint alleging violations of the Animal Welfare Act:

On May 18, 2022, the U.S. Department of Justice ("DOJ"), together with federal and state law enforcement agents, executed a search and seizure warrant on the Cumberland, Virginia facility. The warrant was issued by the U.S. District Court for the Western District of Virginia on May 13, 2022. Consistent with Company policy, the Company is cooperating with DOJ and other involved authorities.

On May 19, 2022, a complaint was filed against Envigo in the U.S. District Court for the Western District of Virginia. The complaint is a civil action by DOJ alleging violations of the Animal Welfare Act at the Cumberland, Virginia facility. The complaint seeks declaratory and injunctive relief and costs. The Company is in the process of reviewing the matters set forth in the complaint and at this time cannot reasonably estimate the associated costs.

(Emphasis added.)

28. On May 21, 2022, Judge Moon of the United States District Court for the Western District of Virginia issued an amended temporary restraining order (issued ex parte) which stated the following pertinent details regarding the Cumberland Facility:

On May 19, 2022, the United States of America filed a complaint and motion requesting an ex parte temporary restraining order directed against Envigo, a company that breeds and sells animals for use in scientific research. *Envigo's facility in Cumberland, Virginia, raises thousands of beagles for these purposes at any given time. This Court now concludes that the Government has provided sufficient evidence that Envigo is engaged in serious and ongoing violations of the Animal Welfare Act, and that an immediate temporary restraining order must issue to put a halt to such violations pending further proceedings.* 

Over 300 beagle puppies have died onsite due to "unknown causes" over seven months. Many were not given anesthesia before they were euthanized by intracardiac injection. Beagles with even minor injuries or easily treated medical conditions were euthanized rather than given veterinary care. Nursing female beagles were denied food, and so they (and their litters) were unable to get adequate nutrition. The food that the beagles did receive was observed to contain live insects, worms, maggots, beetles, flies, ants, mold, and feces.

Beagle puppies remained housed in their enclosures as they were hosed down with cold water, leaving them shivering. *Over an eight-week period*, *25 beagle puppies died from cold exposure*. The enclosures were overcrowded. The facility was understaffed. Inspectors found over 900 beagle and beagle puppy records to be incomplete or inaccurate. The list of serious violations of the Animal Welfare Act and its regulations goes on and on. Indeed, pursuant to federal search warrant executed days ago (May 18, 2022), law enforcement has seized 145 dogs and puppies from the facility that veterinarians determined needed immediate care to alleviate life-threatening illnesses or injuries.

The Government has demonstrated that extraordinary relief in the form of an exparte temporary restraining order is warranted to put an immediate halt to such practices. Defendants will have the opportunity to plead their case on an expedited basis.

\* \* \*

The Government contends that Envigo has consistently failed, despite repeated warnings and opportunities for correction, to meet its obligations under AWA's implementing regulations to provide adequate veterinary care. See Dkt. 2-1 pp. 10–11. Based on the overwhelming evidence produced by the Government, the Court agrees.

\* \* \*

Envigo's level of veterinary care for its beagles has not improved since those earlier inspections. Veterinary exams ensuing from the May 18, 2022, search warrant determined that 145 beagles were in "acute distress," meaning that the beagles required "immediate veterinary treatment or other care to promptly alleviate a life-threatening illness/injury or any suffering." Moffitt Decl. ¶ 8. The Court understands this number is likely to grow as the Government's veterinarians continue to examine dogs throughout the weekend. Dkt. 2-1 p. 6. Even those beagles not currently in "acute distress" are suffering from significant and serious health conditions, including wounds that required wound care and antibiotics or anti-inflammatory medications, or swollen or enflamed paws, or had dental disease, or other health issues.

\* \* \*

... Despite these harrowing statistics, Envigo's attending veterinarian apparently does not require Envigo staff to notify her when a puppy isfound dead. Compl. ¶ 72; Dkt. 2-3 p.1. The Government maintains, and the Court agrees, that such a policy is inconsistent with Envigo's obligation to utilize methods appropriate to the prevention of disease and injury. See Compl. ¶ 72. Those medical records which are present (even if incomplete) and other evidence submitted further demonstrate that Envigo was failing to attend to beagles' wellbeing or provide them adequate veterinary care with respect to any injuries, illnesses, or serious health conditions which caused the deaths of these particular beagles and beagle puppies and further suggest Envigo's failure to make efforts to learn from these (hundreds) of premature deaths to ensure other litters' health and safety.

\* \* \*

... Perhaps the most heinous discovery of the November 2021 inspection was that Envigo had allowed staff to euthanize dogs without anesthesia, in violation of the facility's own program of care. Id. ¶ 62; Dkt. 2-5 p. 1 ("Inspectors reviewed 171 medical records documenting euthanasia of 196 dogs and puppies and found that many young puppies are not receiving anesthesia prior to being euthanized via intracardiac injection as required by the SOP.").

\* \* \*

The Government's evidence also displays a disturbing failure by Envigo to meet its obligation to provide each beagle with clean, palatable food of adequate quantity and nutritive value. See Dkt. 2-1 pp. 11–12.

...The July 2021 inspectors discovered that nursing females were being denied food for 42-hour periods—apparently in an effort to reduce milk production. Dkt. 2-2 p. 6. In lieu of the daily feeding required by § 3.9(a), food receptacles were placed in front of the mothers' enclosures, so that they could see and smell the food but not eat it. Id. 7. See also id. ("Three dams were observed to be reaching their front paws through the doors of the cages to reach the food in the top of their feeders, these dogs were seen trying to scoop or dig out food from the feeders but could only retrieve the occasional piece of kibble."). The reduced milk production resulting from this practice almost certainly meant that nursing puppies were not having their nutritional needs met either. See Compl. ¶¶ 80–81.

\* \* \*

As described above, the Court finds the Government has clearly demonstrated that irreparable harm will result absent injunctive relief. *Specifically, Envigo has been operating and continues to operate in a manner that flagrantly disregards numerous health protocols, placing the health of animals in serious danger and risk of death.* See 7 U.S.C. § 2146(c). USDA inspection records documented dozens of instances in which dogs were euthanized rather than provided medical care when they had an injury, no matter how substantial or minor. E.g., Dkt. 2-3 p. 6; Hollingsworth Decl. ¶ 5.

(Emphasis added.) (Internal footnotes omitted.)

- 29. On this news, the Company's share price fell \$5.19 per share, or 28%, to close at \$13.14 per share on May 23, 2022, the next trading day, on unusually heavy trading volume, damaging investors.
- 30. On June 13, 2022, after trading hours, Inotiv issued a press release entitled "Inotiv, Inc. Announces Site Closures and Consolidation Plans" which stated the following regarding Inotiv closing two Envigo facilities mere months after the acquisition:

Inotiv, Inc. (NASDAQ: NOTV) (the "Company", "We", "Our" or "Inotiv"), a leading contract research organization specializing in nonclinical and analytical drug discovery and development services and research models and related products and services, announces the closure of two Envigo RMS ("Envigo") facilities in Virginia: a purpose-bred canine facility in Cumberland and a rodent breeding

facility in Dublin as part of restructuring activities following its acquisition of Envigo RMS LLC in November 2021.

Robert Leasure, Jr., Inotiv's President and Chief Executive Officer commented, "Since the Envigo acquisition in November 2021, the Cumberland, Virginia, facility was recognized as needing improvements and investments. Inotiv has been pleased with the continued and significant progress in improvements at the Cumberland facility since the acquisition, as evidenced by recent inspections by the USDA and other auditing organizations. We sincerely appreciate our customers', employees', and third-party input to date in support of this facility. The required investments to improve the facility and the lead time to achieve these improvements have recently increased. As a result, we have decided we will not be investing further in this facility, and it will be closed. We will implement an orderly closure plan. Cumberland comprises less than 1% of our total Inotiv revenue and has not contributed to profits in our Research Models and Services segment since the acquisition."

Leasure continued, "The announced closure of the Dublin, Virginia, facility is part of Inotiv's ongoing restructuring and site optimization plan which includes the previously announced closure of facilities in Haslett, Michigan, and Boyertown, Pennsylvania. Closing the Dublin facility will also reduce anticipated capital expenditure needs at this site. *The current production in Dublin will be relocated to other facilities which have recently been expanded or refurbished.* We believe our site restructuring and optimization plan will provide the Company with additional operational efficiencies and will allow customers to be better served from existing, refurbished locations. We expect these three facilities' transitions to be complete by December 2022."

(Emphasis added.)

- 31. On this news, the Company's share price fell \$0.25 per share, or 2%, to close at \$12.78 per share on June 14, 2022, further damaging investors.
- 32. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### PLAINTIFF'S CLASS ACTION ALLEGATIONS

33. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants

who acquired Inotiv securities publicly traded on the NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

- 34. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Inotiv securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.
- 35. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 36. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 37. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - whether the Exchange Act was violated by Defendants' acts as alleged herein;
  - whether statements made by Defendants to the investing public during the Class
     Period misrepresented material facts about the business and financial condition of the Company;

- whether Defendants' public statements to the investing public during the Class

  Period omitted material facts necessary to make the statements made, in light of
  the circumstances under which they were made, not misleading;
- whether the Defendants caused the Company to issue false and misleading filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of Inotiv securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 38. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 39. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
  - Inotiv securities met the requirements for listing, and were listed and actively traded on the NASDAQ, an efficient market;
  - As a public issuer, the Company filed public reports;
  - the Company communicated with public investors via established market communication mechanisms, including through the regular dissemination of press

releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period; and
- the Company was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.
- 40. Based on the foregoing, the market for the Company securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of the common units, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 41. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

# COUNT I For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder Against All Defendants

- 42. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 43. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

- 44. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
  - 45. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:
    - employed devices, schemes and artifices to defraud;
    - made untrue statements of material facts or omitted to state material facts
      necessary in order to make the statements made, in light of the
      circumstances under which they were made, not misleading; or
    - engaged in acts, practices and a course of business that operated as a fraud
      or deceit upon plaintiff and others similarly situated in connection with their
      purchases of the Company's securities during the Class Period.
- 46. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

- 47. Individual Defendants, who are or were senior executives and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Inotiv personnel to members of the investing public, including Plaintiff and the Class.
- 48. As a result of the foregoing, the market price of Inotiv securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Inotiv securities during the Class Period in purchasing Inotiv securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.
- 49. Had Plaintiff and the other members of the Class been aware that the market price of Inotiv securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Company securities at the artificially inflated prices that they did, or at all.
- 50. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.
- 51. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of Inotiv securities during the Class Period.

# COUNT II Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

- 52. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.
- 53. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's misstatement of revenue and profit and false financial statements.
- 54. As officers of a public business, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.
- 55. Because of their positions of control and authority as senior executives and/or directors, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Company securities.

56. By reason of the above conduct, the Individual Defendants are liable pursuant to

Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment and

relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead

Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of

Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all

defendants, jointly and severally, together with interest thereon;

(c) awarding plaintiff and the Class reasonable costs and expenses incurred in this

action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as

the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: June 23, 2022

Respectfully submitted

/s/ Brad A. Catlin

Brad A. Catlin, Atty. No. 21570-29

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